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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,795	07/22/2003	Alastair McIndoe Hodges	104978-0007	7470

21125 7590 11/21/2006

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,795

Applicant(s)

HODGES ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/981,385.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/25/2006</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS of 8/04/2006</u> . |

DETAILED ACTION

Response to Arguments

1. Applicants' arguments filed October 09, 2006 ("Arguments") have been fully considered but they are not persuasive.

Applicants assert,

"Applicants disagree with the Examiner's arguments, as Diebold does not provide the motivation of the desirability of a smaller sample size because decreasing the thickness between the electrodes and the thickness of the intermediate layers would adversely affect the Cottrell analysis." *Bottom of page 3 of the Arguments.*

The Examiner respectfully disagrees. A major advantage of Diebold's biosensor is that it will make a measurement on a very small sample. This is pointed out in Diebold several times. See the last sentence of the abstract; col. 02:01-18; and col. 12:35-41. Additionally, Applicants have not demonstrated that if the Diebold biosensor is scaled down so that opposing electrodes are spaced by 20-200 microns that the biosensor will not follow Cottrell behavior. While the Examiner

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acknowledges that the White patent, which is cited by Diebold for an example measurement circuit, only flags deviation from Cottrell behavior and does not correct it, as discussed on pages 4-5 of the Arguments, there is no suggestion in White that non-Cottrell behavior will result from electrodes that are too closely spaced together. Instead, White attributes non-Cottrell behavior to insufficient coverage of the sensing electrode by the sample, hydration of the reaction area before or during the test, and "... leakage along the length of the electrodes so that the blood sample covers not only the portion of the electrodes in the reaction zone, but also outside the reaction zone..." See col. 02:35-51. From pages 5-6 of the Arguments Applicants attempt to show that if the biosensor of Diebold is scaled down so that opposing electrodes are spaced apart by 0.1mm then a significant change in current will result. However, assuming the calculations are correct, that the Cottrell current with an electrode spacing of 0.1 mm ("id") is more than 20% different than the Cottrell current at an electrode spacing of 1mm ("ic") does not establish that non-Cottrell current behavior at an electrode spacing of 20-200 microns. The Examiner would like to note that Pottgen found an electrode spacing of 0.1 mm sufficient for Cottrell current flow. See col. 07:43-65.

On the bottom of page 6, bridgn to page 7 and on page 8 of the Arguments Applicants argue that one with ordinary skill in the art would have no motivation to combine Diebold Straus, Enthone, and Kanezawa because Straus, Enthone, and

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Kanezawa are from different technologies and so are non-analogous art to Diebold. The Examiner respectfully disagrees. As acknowledged by Applicants, "Enthone and Kanezawa are both directed towards *printed circuit boards*." See page 6 of the Arguments. Now Diebold states, "This invention is based on the novel adaptaion of some *technisques common the PCB [printed circuit board] industry* to produce high-resolutoin elecords for use in an electrochemcial sensor. [emphasis added]." See col. 01:65 – col. 02:1 and col. 01:37. Thus, Enthone and Kanezawa are very relevant to Diebold. Although Straus is directed to packing materials Straus is still relevant because it is only cited to show the commercial availability of very thin (12.2 microns thick) Mylar sheets, which are used by Diebold for the electrode supports and the spacer layer.

From page 7 to page 8 of the Arguments Applicants argue that Diebold, Straus, Enthone, and Kanezawa do not teach or even suggest the recitations of Applicants' claims because they each do not meet all of the limitations of claim 1. However, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Similarly with respect the rejection of claim 5 under 35 U.S.C. 103(a) Applicants fault Carter and Bohs for not meeting all of the limitations of claim 5. However Carter and Bohs are only cited to show that using a non-metal working electrode with a silver counter/reference electrode is no not novel.

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Last, Applicants have not filed terminal disclaimers against copending applications 10/624,746 and 10/624,823.

For the reasons set forth above all rejections pending since the Office action of July 10, 2006 are maintained.

Final Rejection

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension-of-time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola

Alex Noguerola
Primary Examiner
AU 1753

November 17, 2006

M-F 8:30 - 5:00

(571) 272-1342. The fax phone number for the

application or proceeding is assigned to 571-2

application may be obtained from the

Status information for published

through Private PAIR only. For more in

you have questions on access to the Private PAIR